

#### REMARKS

It is the Examiner's position that the present claims encompass five (5) groups of inventions. These are as follows:

Group I: Claim 1, drawn to a rpoB promoter element, classified in class 536, subclass 24.1.

Group II: Claim 2, drawn to an atbB promoter element, classified in class 536, subclass 24.1.

Group III: Claim 3, drawn to a clpP promoter element, classified in class 536, subclass 24.1.

Group IV: Claim 4, drawn to a 16S rRNA promoter element, classified in class 536, subclass 24.1.

Group V: Claims 5-7, drawn to constructs comprising an NEP promoter element and a PEP promoter element, classified in class 536, subclass 24.1.

Specifically, the Examiner contends that the claims encompass distinct inventions because they are drawn to promoters comprising nucleotide sequences which "are structurally distinct chemical compounds which are unrelated to one another". The sequences encompassed by the present claims are relatively short. Applicants respectfully submit that the present restriction requirement is improper for failing to comply with the relevant provisions of the Manual of Patent Examination Procedures (MPEP). The Examiner contends at page 2 of the instant Official Action that each sequence requires an independent search of the sequence data base". It appears as if the Examiner is alleging that a search of the promoter sequences presently claimed imposes an undue search burden. Applicants respectfully submit, however, that MPEP clearly teaches that the search of more than one nucleic acid sequence is **not** an undue burden. Indeed, §803.04 of the MPEP states:

"to further aid the biotechnology industry in protecting its intellectual property **without creating an undue burden on the Office**, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such

nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, **up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction.**" [Emphasis added.]

Furthermore, the MPEP at §803.04 also indicates that in "some **exceptional** cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten." [Emphasis added.]

The present case is not exceptional. As mentioned above, the sequences encompassed by the claims are relatively short. Accordingly, Applicants request withdrawal, or at the very least modification of the present restriction requirement.

In order to be fully responsive, Applicants hereby elect, with traverse, the Group V invention, namely claims 5-7 directed to promoter constructs containing both NEP and PEP promoters.

Applicants reserve the right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.

At page 3 of the Restriction Requirement, the Examiner contends that specification is not in compliance with the Sequence Listing Rules. Applicants submit that the preliminary amendment filed with the Application provides the sequence identifiers required on page 22. Page 33 of the specification has been amended to recite the particular nucleotides of SEQ ID NO: 25 shown. It is submitted that the foregoing amendments render the Examiner objection to the specification moot.

Early and favorable action on the merits of this

application is respectfully solicited.

Respectfully submitted,

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